PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

WRITTEN OPINION
(PCT Rule 66)

2 REPLY DUE!

Date of mailing *(day/month/year)*	04.11.2004 NOV 19, 2004
Applicant's or agent's file reference	PCT-1088 (METHYLPHENIDATE)
REPLY DUE	**within 0 month(s) and 15 days** from the above date of mailing
International application No.	PCT/CA 03/01175
International filing date *(day/month/year)*	06.08.2003
Priority date *(day/month/year)*	13.08.2002
International Patent Classification (IPC) or both national classification and IPC	A61K9/00, A61K9/16
Applicant	SHERMAN, Bernard Charles

1. This written opinion is the **second** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 13.12.2004

Name and mailing address of the international preliminary examining authority:

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Form PCT/IPEA/408 (Cover Sheet) (January 2004)

WRITTEN OPINION International application No. PCT/CA 03/01175

I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-4 as originally filed

Claims, Numbers

1-8 filed with telefax on 05.10.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☒ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

WRITTEN OPINION

International application No. PCT/CA 03/01175

1. Statement

Novelty (N)	Claims	1,2
Inventive step (IS)	Claims	1-6
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION
SEPARATE SHEET

International application No. PCT/CA 03/01175

I. Basis of the report

This report has been established as if the amendments of claims had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c) PCT).

V. Reasoned statement (Continuation)

1. CITATIONS

Reference is made to the following documents:

D1: WO 00/35450 A (KRISHNAMURTHY THINNAYAM N ; DARKE ANDREW (CA); EURO CELTIQUE SA (LU);) 22 June 2000 (2000-06-22)

2. AMENDMENTS (Art. 34(2)b PCT)

2.1 The amendments filed with the fax received on 04 October 2004 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:

2.1.1 Claim 1 "water soluble drug"

2.1.2 Claim 7 and 8. No basis could be found for the amendment of claim 1. Furthermore, the amendment of claim 7 is based on a specific embodiment of the invention and has thus to be considered as an undue generalisation of the subject-matter disclosed in said example.

3 NOVELTY (Art. 33(2) PCT)

3.1 D1 discloses oral controlled release methylphenidate formulations comprising methylphenidate hydrochloride and Eudragit L 100-55 as enteric polymer. Granules are made by melt-extrusion and milling. Therefore a composition is provided comprising particles, wherein the particles consist of a homogenous mixture which comprises the drug and an enteric polymer (D1, examples 10, 11).

3.2 The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1 and 2 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

3.3 INVENTIVE STEP (Art. 33(3) PCT)

3.4 Even if the applicant could restore novelty of independent claim 1, an objection on ground of lack of an inventive step is likely to arise with view on the objections against lack of support raised above.

3.5 It is further remarked that, if in straight contradiction to the description (see above) the entire subject-matter of the claim would actually solve the underlying problem, the solution could not be considered to involve an inventive step, because in this case the skilled person was apparently rather unrestricted in his choice of appropriate ingredients from those commonly used for such purposes, so that no undue amount of experimentation or exercise of inventive skill was required.

3.6 The present application does therefore not satisfy the criterion set forth in Article 33(3) PCT and the subject-matter of claims 1-6 does not involve an inventive step (Rule 65(1)(2) PCT).

4 Further remarks

Claims 1-6 do not satisfy the criterion set forth in Article 6 PCT for the following reasons:

4.1 Claim 1 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved which merely amounts to a statement of the underlying problem ("release in two spikes"). The technical features necessary for achieving this result are however missing.

4.2 Claims 1-6 are not supported by the description as required by Article 6 PCT, as their

scope is broader than justified by the description. The reasons therefor are the following:

4.2.1 The description discloses specifically a formulation comprising methylphenidate and an enteric polymer, in particular polyvinyl acetate phthalate. This formulation shall release a certain amount of drug immediately and another amount in a delayed release mode. The Applicant states that the ratio of the enteric polymer to drug and the particle size range are chosen by a trial and error method (page 3, lines 13-16). It is clear to the person skilled in the art that the release characteristics are furthermore dependent from the nature of the drug and the polymer selected.

4.2.2 The requirement of support can only mean that the **whole** subject-matter that is defined in the claims, and not only a part of it, must be capable of being carried out by the skilled person without the burden of an undue amount of experimentation or the application of inventive ingenuity. Consequently, all possible alternatives encompassed by the subject-matter for which protection is sought must be available to the skilled person if the definition of the functional term, and the claim of which it forms a part, is to meet the requirements of Article 6 PCT.

4.2.3 Neither the patent specification nor the relevant common general knowledge provide guidance as to which other materials than the material of claims 2 and 3 could be used for achieving the desired effect.